LIOTHYRONINE SODIUM - liothyronine sodium tablet
Mylan Pharmaceuticals Inc.

DESCRIPTION

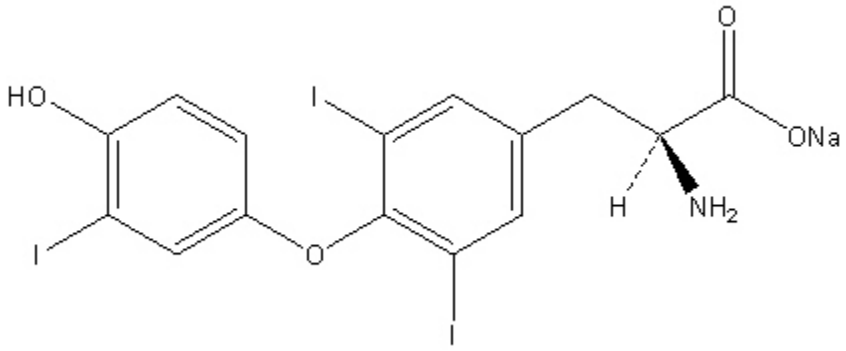
Thyroid hormone drugs are natural or synthetic preparations containing tetraiodothyronine (T_4, levothyroxine) sodium or triiodothyronine (T_3, liothyronine) sodium or both. T_4 and T_3 are produced in the human thyroid gland by the iodination and coupling of the amino acid tyrosine. T_4 contains four iodine atoms and is formed by the coupling of two molecules of diiodotyrosine (DIT). T_3 contains three atoms of iodine and is formed by the coupling of one molecule of DIT with one molecule of monoiodotyrosine (MIT). Both hormones are stored in the thyroid colloid as thyroglobulin.

Thyroid hormone preparations belong to two categories: (1) natural hormonal preparations derived from animal thyroid, and (2) synthetic preparations. Natural preparations include desiccated thyroid and thyroglobulin. Desiccated thyroid is derived from domesticated animals that are used for food by man (either beef or hog thyroid), and thyroglobulin is derived from thyroid glands of the hog. The United States Pharmacopeia (USP) has standardized the total iodine content of natural preparations. Thyroid, USP contains not less than (NLT) 0.17 percent and not more than (NMT) 0.23 percent iodine, and thyroglobulin contains not less than (NLT) 0.7 percent of organically bound iodine. Iodine content is only an indirect indicator of true hormonal biologic activity.

Liothyronine sodium tablets, USP contain liothyronine (L-triiodothyronine or LT_3), a synthetic form of a natural thyroid hormone, and is available as the sodium salt.

The structural and molecular formulas and molecular weight of liothyronine sodium are given below.

Liothyronine Sodium



$C_{15}H_{11}I_3NN_3O_4$ M.W. 672.96

L-Tyrosine, O-(4-hydroxy-3-iodophenyl)-3,5-diiodo-, monosodium salt

Twenty-five mcg of liothyronine is equivalent to approximately one grain of desiccated thyroid or thyroglobulin and 0.1 mg of L-thyroxine.

Liothyronine sodium tablets, USP contain liothyronine sodium, USP equivalent to 5 mcg, 25 mcg or 50 mcg of liothyronine. Inactive ingredients consist of calcium sulfate anhydrous, gelatin, pregelatinized starch, stearic acid, sucrose and talc.

CLINICAL PHARMACOLOGY

The mechanisms by which thyroid hormones exert their physiologic action are not well understood. These hormones enhance oxygen consumption by most tissues of the body, increase the basal metabolic rate and the metabolism of carbohydrates, lipids and proteins. Thus, they exert a profound influence on every organ system in the body and are of particular importance in the development of the central nervous system.

Pharmacokinetics

Since liothyronine sodium (T_3) is not firmly bound to serum protein, it is readily available to body tissues. The onset of activity of liothyronine sodium is rapid, occurring within a few hours. Maximum pharmacologic response occurs within 2 or 3 days, providing early clinical response. The biological half-life is about 2-1/2 days.

T_3 is almost totally absorbed, 95 percent in 4 hours. The hormones contained in the natural preparations are absorbed in a manner similar to the synthetic hormones.

Liothyronine sodium has a rapid cutoff of activity which permits quick dosage adjustment and facilitates control of the effects of overdosage, should they occur.

The higher affinity of levothyroxine (T_4) for both thyroid-binding globulin and thyroid-binding prealbumin as compared to triiodothyronine (T_3) partially explains the higher serum levels and longer half-life of the former hormone. Both protein bound hormones exist in reverse equilibrium with minute amounts of free hormone, the latter accounting for the metabolic activity.

INDICATIONS AND USAGE

Thyroid hormone drugs are indicated:

1. As replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema and ordinary hypothyroidism in patients of any age (pediatric patients, adults, the elderly), or state (including pregnancy); primary hypothyroidism resulting from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary) or tertiary (hypothalamic) hypothyroidism (see WARNINGS).

2. As pituitary thyroid-stimulating hormone (TSH) suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's) and multinodular goiter.

3. As diagnostic agents in suppression tests to differentiate suspected mild hyperthyroidism or thyroid gland autonomy.

Liothyronine sodium tablets can be used in patients allergic to desiccated thyroid or thyroid extract derived from pork or beef.

CONTRAINDICATIONS

Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis and apparent hypersensitivity to any of their active or extraneous constituents. There is no well-documented evidence from the literature, however, of true allergic or idiosyncratic reactions to thyroid hormone.

WARNINGS

Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of thyroid hormones in the therapy of obesity, alone or combined with other drugs, is unjustified and has been shown to be ineffective. Neither is their use justified for the treatment of male or female infertility unless this condition is accompanied by hypothyroidism.

Thyroid hormones should be used with great caution in a number of circumstances where the integrity of the cardiovascular system, particularly the coronary arteries, is suspected. These include patients with angina pectoris or the elderly, in whom there is a greater likelihood of occult cardiac disease. In these patients, liothyronine sodium therapy should be initiated with low doses, with due consideration for its relatively rapid onset of action. Starting dosage of liothyronine sodium tablets is 5 mcg daily, and should be increased by no more than 5 mcg increments at 2-week intervals. When, in such patients, a euthyroid state can only be reached at the expense of an aggravation of the cardiovascular disease, thyroid hormone dosage should be reduced.

Morphologic hypogonadism and nephrosis should be ruled out before the drug is administered. If hypopituitarism is present, the adrenal deficiency must be corrected prior to starting the drug.

Myxedematous patients are very sensitive to thyroid; dosage should be started at a very low level and increased gradually.

Severe and prolonged hypothyroidism can lead to a decreased level of adrenocortical activity commensurate with the lowered metabolic state. When thyroid-replacement therapy is administered, the metabolism increases at a greater rate than adrenocortical activity. This can precipitate adrenocortical insufficiency. Therefore, in severe and prolonged hypothyroidism, supplemental adrenocortical steroids may be necessary. In rare instances the administration of thyroid hormone may precipitate a hyperthyroid state or may aggravate existing hyperthyroidism.

PRECAUTIONS

General

Thyroid hormone therapy in patients with concomitant diabetes mellitus or insipidus or adrenal cortical insufficiency aggravates the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases are required.

The therapy of myxedema coma requires simultaneous administration of glucocorticoids.

Hypothyroidism decreases and hyperthyroidism increases the sensitivity to oral anticoagulants. Prothrombin time should be closely monitored in thyroid-treated patients on oral anticoagulants and dosage of the latter agents adjusted on the basis of frequent prothrombin time determinations. In infants, excessive doses of thyroid hormone preparations may produce craniosynostosis.

Information for the Patient

Patients on thyroid hormone preparations and parents of pediatric patients on thyroid therapy should be informed that:

1. Replacement therapy is to be taken essentially for life, with the exception of cases of transient hypothyroidism, usually associated with thyroiditis, and in those patients receiving a therapeutic trial of the drug.

2. They should immediately report during the course of therapy any signs or symptoms of thyroid hormone toxicity, e.g., chest pain, increased pulse rate, palpitations, excessive sweating, heat intolerance, nervousness, or any other unusual event.

3. In case of concomitant diabetes mellitus, the daily dosage of antidiabetic medication may need readjustment as thyroid hormone replacement is achieved. If thyroid medication is stopped, a downward readjustment of the dosage of insulin or oral hypoglycemic agent may be necessary to avoid hypoglycemia. At all times, close monitoring of urinary glucose levels is mandatory in such patients.

4. In case of concomitant oral anticoagulant therapy, the prothrombin time should be measured frequently to determine if the dosage of oral anticoagulants is to be readjusted.

5. Partial loss of hair may be experienced by pediatric patients in the first few months of thyroid therapy, but this is usually a transient phenomenon and later recovery is usually the rule.

Laboratory Tests
Treatment of patients with thyroid hormones requires the periodic assessment of thyroid status by means of appropriate laboratory tests besides the full clinical evaluation. The TSH suppression test can be used to test the effectiveness of any thyroid preparation, bearing in mind the relative insensitivity of the infant pituitary to the negative feedback effect of thyroid hormones. Serum T_4 levels can be used to test the effectiveness of all thyroid medications except products containing liothyronine sodium. When the total serum T_4 is low but TSH is normal, a test specific to assess unbound (free) T_4 levels is warranted. Specific measurements of T_4 and T_3 by competitive protein binding or radioimmunoassay are not influenced by blood levels of organic or inorganic iodine and have essentially replaced older tests of thyroid hormone measurements, i.e., PBI, BEI and T_4 by column.

Drug Interactions

Oral Anticoagulants
Thyroid hormones appear to increase catabolism of vitamin K-dependent clotting factors. If oral anticoagulants are also being given, compensatory increases in clotting factor synthesis are impaired. Patients stabilized on oral anticoagulants who are found to require thyroid replacement therapy should be watched very closely when thyroid is started. If a patient is truly hypothyroid, it is likely that a reduction in anticoagulant dosage will be required. No special precautions appear to be necessary when oral anticoagulant therapy is begun in a patient already stabilized on maintenance thyroid replacement therapy.

Insulin or Oral Hypoglycemics
Initiating thyroid replacement therapy may cause increases in insulin or oral hypoglycemic requirements. The effects seen are poorly understood and depend upon a variety of factors such as dose and type of thyroid preparations and endocrine status of the patient. Patients receiving insulin or oral hypoglycemics should be closely watched during initiation of thyroid replacement therapy.

Cholestyramine
Cholestyramine binds both T_4 and T_3 in the intestine, thus impairing absorption of these thyroid hormones. *In vitro* studies indicate that the binding is not easily removed. Therefore, 4 to 5 hours should elapse between administration of cholestyramine and thyroid hormones.

Estrogen, Oral Contraceptives
Estrogens tend to increase serum thyroxine-binding globulin (TBg). In a patient with a nonfunctioning thyroid gland who is receiving thyroid replacement therapy, free levothyroxine may be decreased when estrogens are started thus increasing thyroid requirements. However, if the patient's thyroid gland has sufficient function, the decreased free thyroxine will result in a compensatory increase in thyroxine output by the thyroid. Therefore, patients without a functioning thyroid gland who are on thyroid replacement therapy may need to increase their thyroid dose if estrogens or estrogen-containing oral contraceptives are given.

Tricyclic Antidepressants
Use of thyroid products with imipramine and other tricyclic antidepressants may increase receptor sensitivity and enhance antidepressant activity; transient cardiac arrhythmias have been observed. Thyroid hormone activity may also be enhanced.

Digitalis
Thyroid preparations may potentiate the toxic effects of digitalis. Thyroid hormonal replacement increases metabolic rate, which requires an increase in digitalis dosage.

Ketamine
When administered to patients on a thyroid preparation, this parenteral anesthetic may cause hypertension and tachycardia. Use with caution and be prepared to treat hypertension, if necessary.

Vasopressors
Thyroxine increases the adrenergic effect of catecholamines such as epinephrine and norepinephrine. Therefore, injection of these agents into patients receiving thyroid preparations increases the risk of precipitating coronary insufficiency, especially in patients with coronary artery disease. Careful observation is required.

Drug/Laboratory Test Interactions
The following drugs or moieties are known to interfere with laboratory tests performed in patients on thyroid hormone therapy: androgens, corticosteroids, estrogens, oral contraceptives containing estrogens, iodine-containing preparations and the numerous preparations containing salicylates.

1. Changes in TBg concentration should be taken into consideration in the interpretation of T_4 and T_3 values. In such cases, the unbound (free) hormone should be measured. Pregnancy, estrogens and estrogen-containing oral contraceptives increase TBg concentrations. TBg may also be increased during infectious hepatitis. Decreases in TBg concentrations are observed in nephrosis, acromegaly and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBg deficiency approximates 1 in 9,000. The binding of thyroxine by thyroxine-binding prealbumin (TBPA) is inhibited by salicylates.

2. Medicinal or dietary iodine interferes with all *in vivo* tests of radioiodine uptake, producing low uptakes which may not be reflective of a true decrease in hormone synthesis.

3. The persistence of clinical and laboratory evidence of hypothyroidism in spite of adequate dosage replacement indicates either poor patient compliance, poor absorption, excessive fecal loss, or inactivity of the preparation. Intracellular resistance to thyroid hormone is quite rare.

Carcinogenesis, Mutagenesis and Impairment of Fertility
A reportedly apparent association between prolonged thyroid therapy and breast cancer has not been confirmed and patients on thyroid for established indications should not discontinue therapy. No confirmatory long-term studies in animals have been performed to evaluate carcinogenic potential, mutagenicity, or impairment of fertility in either males or females.

Pregnancy

Category A
Thyroid hormones do not readily cross the placental barrier. The clinical experience to date does not indicate any adverse effect on fetuses when thyroid hormones are administered to pregnant women. On the basis of current knowledge, thyroid replacement therapy to hypothyroid women should not be discontinued during pregnancy.

Nursing Mothers
Minimal amounts of thyroid hormones are excreted in human milk. Thyroid is not associated with serious adverse reactions and does not have a known tumorigenic potential. However, caution should be exercised when thyroid is administered to a nursing woman.

Geriatric Use
Clinical studies of liothyronine sodium did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Pediatric Use
Pregnant mothers provide little or no thyroid hormone to the fetus. The incidence of congenital hypothyroidism is relatively high (1:4000) and the hypothyroid fetus would not derive any benefit from the small amounts of hormone crossing the placental barrier. Routine determinations of serum T_4 and/or TSH is strongly advised in neonates in view of the deleterious effects of thyroid deficiency on growth and development.
Treatment should be initiated immediately upon diagnosis and maintained for life, unless transient hypothyroidism is suspected, in which case, therapy may be interrupted for 2 to 8 weeks after the age of 3 years to reassess the condition. Cessation of therapy is justified in patients who have maintained a normal TSH during those 2 to 8 weeks.

ADVERSE REACTIONS
Adverse reactions, other than those indicative of hyperthyroidism because of therapeutic overdosage, either initially or during the maintenance period are rare (see OVERDOSAGE).
In rare instances, allergic skin reactions have been reported with liothyronine sodium tablets.

OVERDOSAGE

Signs and Symptoms
Headache, irritability, nervousness, sweating, arrhythmia (including tachycardia), increased bowel motility and menstrual irregularities. Angina pectoris or congestive heart failure may be induced or aggravated. Shock may also develop. Massive overdosage may result in symptoms resembling thyroid storm. Chronic excessive dosage will produce the signs and symptoms of hyperthyroidism.

Treatment of Overdosage
Dosage should be reduced or therapy temporarily discontinued if signs and symptoms of overdosage appear. Treatment may be reinstituted at a lower dosage. In normal individuals, normal hypothalamic-pituitary-thyroid axis function is restored in 6 to 8 weeks after thyroid suppression.
Treatment of acute massive thyroid hormone overdosage is aimed at reducing gastrointestinal absorption of the drugs and counteracting central and peripheral effects, mainly those of increased sympathetic activity. Vomiting may be induced initially if further gastrointestinal absorption can reasonably be prevented and barring contraindications such as coma, convulsions, or loss of the gagging reflex. Treatment is symptomatic and supportive. Oxygen may be administered and ventilation maintained. Cardiac glycosides may be indicated if congestive heart failure develops. Measures to control fever, hypoglycemia, or fluid loss should be instituted if needed. Antiadrenergic agents, particularly propranolol, have been used advantageously in the treatment of increased sympathetic activity. Propranolol may be administered intravenously at a dosage of 1 mg to 3 mg over a 10-minute period or orally, 80 to 160 mg/day, especially when no contraindications exist for its use.

DOSAGE AND ADMINISTRATION
The dosage of thyroid hormones is determined by the indication and must in every case be individualized according to patient response and laboratory findings.
Liothyronine sodium tablets are intended for oral administration; once-a-day dosage is recommended. Although liothyronine sodium has a rapid cutoff, its metabolic effects persist for a few days following discontinuance.

Mild Hypothyroidism
Recommended starting dosage is 25 mcg daily. Daily dosage then may be increased by up to 25 mcg every 1 or 2 weeks. Usual maintenance dose is 25 mcg to 75 mcg daily.
The rapid onset and dissipation of action of liothyronine sodium (T_3), as compared with levothyroxine sodium (T_4), has led some clinicians to prefer its use in patients who might be more susceptible to the untoward effects of thyroid medication. However, the wide swings in serum T_3 levels that follow its administration and the possibility of more pronounced cardiovascular side effects tend to counterbalance the stated advantages.
Liothyronine sodium tablets may be used in preference to levothyroxine (T_4) during radioisotope scanning procedures, since induction of hypothyroidism in those cases is more abrupt and can be of shorter duration. It may also be preferred when impairment of peripheral conversion of T_4 to T_3 is suspected.

Myxedema
Recommended starting dosage is 5 mcg daily. This may be increased by 5 mcg to 10 mcg daily every 1 or 2 weeks. When 25 mcg daily is reached, dosage may be increased by 5 mcg to 25 mcg every 1 or 2 weeks until a satisfactory therapeutic response is attained. Usual maintenance dose is 50 mcg to 100 mcg daily.

Myxedema Coma
Myxedema coma is usually precipitated in the hypothyroid patient of long standing by intercurrent illness or drugs such as sedatives and anesthetics and should be considered a medical emergency.

Congenital Hypothyroidism
Recommended starting dosage is 5 mcg daily, with a 5 mcg increment every 3 to 4 days until the desired response is achieved. Infants a few months old may require only 20 mcg daily for maintenance. At one year, 50 mcg daily may be required. Above 3 years, full adult dosage may be necessary (see PRECAUTIONS: Pediatric Use).

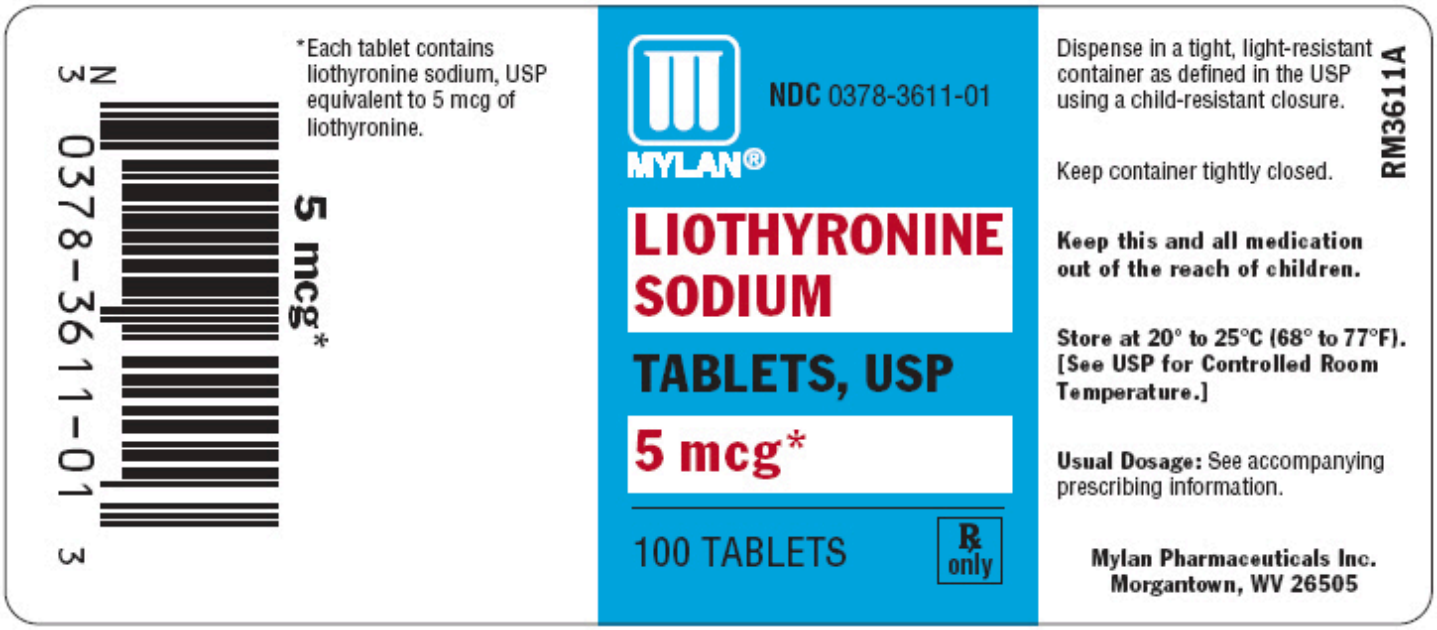
Simple (non-toxic) Goiter
Recommended starting dosage is 5 mcg daily. This dosage may be increased by 5 mcg to 10 mcg daily every 1 or 2 weeks. When 25 mcg daily is reached, dosage may be increased every week or two by 12.5 mcg or 25 mcg. Usual maintenance dosage is 75 mcg daily.
In the elderly or in pediatric patients, therapy should be started with 5 mcg daily and increased only by 5 mcg increments at the recommended intervals.
When switching a patient to liothyronine sodium tablets from thyroid, L-thyroxine or thyroglobulin, discontinue the other medication, initiate liothyronine sodium at a low dosage, and increase gradually according to the patient's response. When selecting

a starting dosage, bear in mind that this drug has a rapid onset of action, and that residual effects of the other thyroid preparation may persist for the first several weeks of therapy.

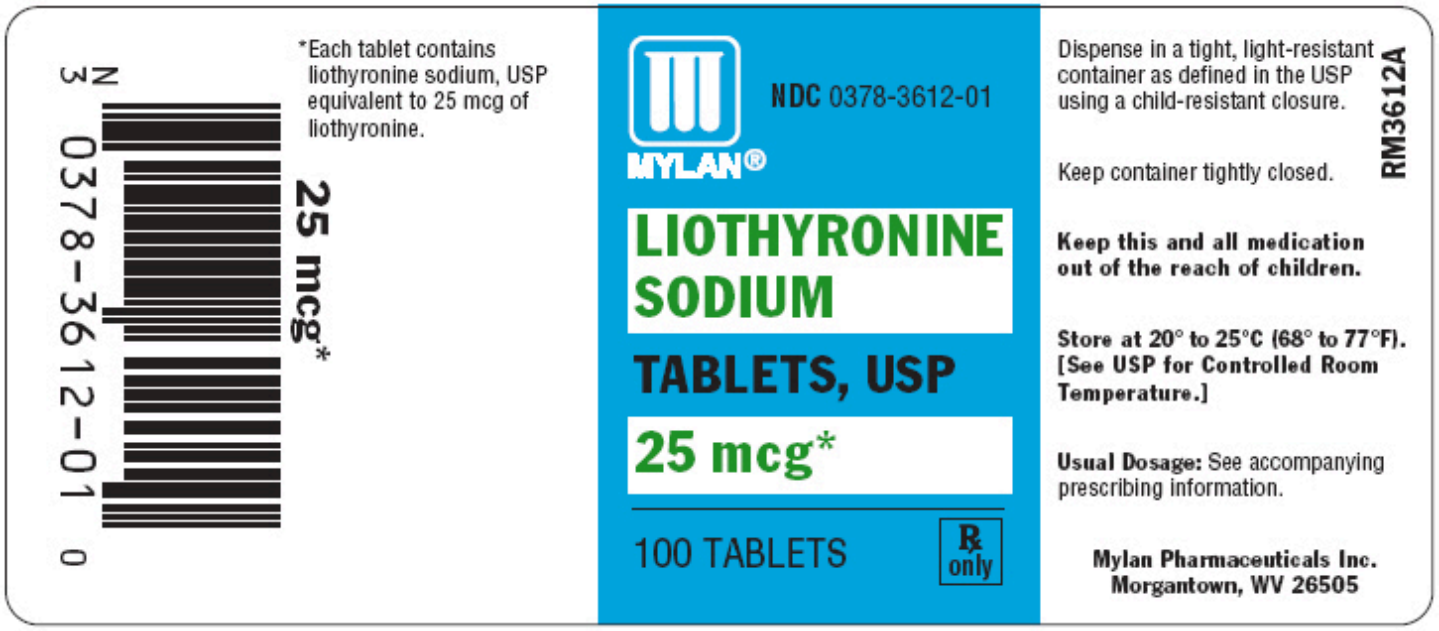
Thyroid Suppression Therapy
Administration of thyroid hormone in doses higher than those produced physiologically by the gland results in suppression of the production of endogenous hormone. This is the basis for the thyroid suppression test and is used as an aid in the diagnosis of patients with signs of mild hyperthyroidism in whom baseline laboratory tests appear normal or to demonstrate thyroid gland autonomy in patients with Graves' ophthalmopathy. ^{131}I uptake is determined before and after the administration of the exogenous hormone. A 50% or greater suppression of uptake indicates a normal thyroid-pituitary axis and thus rules out thyroid gland autonomy. Liothyronine sodium tablets are given in doses of 75 to 100 mcg/day for 7 days, and radioactive iodine uptake is determined before and after administration of the hormone. If thyroid function is under normal control, the radioiodine uptake will drop significantly after treatment. Liothyronine sodium tablets should be administered cautiously to patients in whom there is a strong suspicion of thyroid gland autonomy, in view of the fact that the exogenous hormone effects will be additive to the endogenous source.

HOW SUPPLIED
Liothyronine Sodium Tablets, USP are available containing liothyronine sodium, USP equivalent to 5 mcg, 25 mcg, or 50 mcg of liothyronine.
The 5 mcg tablets are white to off-white, round, unscored tablets debossed with **ML** on one side of the tablet and **11** on the other side. They are available as follows:
NDC 0378-3611-01
bottles of 100 tablets
NDC 0378-3611-10
bottles of 1000 tablets
The 25 mcg tablets are white to off-white, oval, scored, tablets debossed with **M** to the left of the score and **L** to the right of the score on one side and **12** on the other side. They are available as follows:
NDC 0378-3612-01
bottles of 100 tablets
NDC 0378-3612-10
bottles of 1000 tablets
The 50 mcg tablets are white to off-white, caplet-shaped, scored tablets debossed with **M** to the left of the score and **L** to the right of the score on one side and **13** on the other side.They are available as follows:
NDC 0378-3613-01
bottles of 100 tablets
NDC 0378-3613-10
bottles of 1000 tablets
Store at 20° to 25°C (68° to 77°F). [See USP for Controlled Room Temperature.]
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505
AUGUST 2008
LIOT:R1
PRINCIPAL DISPLAY PANEL - 5 mcg
NDC 0378-3611-01
LIOTHYRONINE
SODIUM
TABLETS, USP
5 mcg*
100 TABLETS **(Rx only)**
*Each tablet contains
liothyronine sodium, USP
equivalent to 5 mcg of
liothyronine.
Dispense in a tight, light-resistant
container as defined in the USP
using a child-resistant closure.
Keep container tightly closed.
Keep this and all medication
out of the reach of children.
Store at 20° to 25°C (68° to 77°F).
[See USP for Controlled Room

Temperature.]
Usual Dosage: See accompanying prescribing information.
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505
RM3611A



PRINCIPAL DISPLAY PANEL - 25 mcg
NDC 0378-3612-01
LIOTHYRONINE
SODIUM
TABLETS, USP
25 mcg*
100 TABLETS **(Rx only)**
*Each tablet contains liothyronine sodium, USP equivalent to 25 mcg of liothyronine.
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
Keep container tightly closed.
Keep this and all medication out of the reach of children.
Store at 20° to 25°C (68° to 77°F). [See USP for Controlled Room Temperature.]
Usual Dosage: See accompanying prescribing information.
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505
RM3612A



PRINCIPAL DISPLAY PANEL - 50 mcg
NDC 0378-3613-01
LIOTHYRONINE
SODIUM
TABLETS, USP
50 mcg*
100 TABLETS **(Rx only)**
*Each tablet contains
liothyronine sodium, USP
equivalent to 50 mcg of
liothyronine.
Dispense in a tight, light-resistant
container as defined in the USP
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Keep container tightly closed.
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Store at 20° to 25°C (68° to 77°F).
[See USP for Controlled Room
Temperature.]
Usual Dosage: See accompanying
prescribing information.
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505
RM3613A

*Each tablet contains liothyronine sodium, USP equivalent to 50 mcg of liothyronine.

MYLAN®

NDC 0378-3613-01

LIOTHYRONINE SODIUM

TABLETS, USP

50 mcg*

100 TABLETS

℞ only

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

RM3613A

Keep container tightly closed.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP for Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

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